

### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:

Robert M. Townsend et al.

Examiner:

Phillip Gambel, Ph.D.

Serial No.:

09/877,987

Group Art Unit:

1645

Filed:

June 8, 2001

Docket:

D0009NP; 30436.53USU1

Title:

METHODS FOR REGULATING A CELL-MEDIATED IMMUNE RESPONSE BY

BLOCKING LYMPHOCYTIC SIGNALS AND BY BLOCKING LFA-1-MEDIATED

**ADHESION** 

#### **CERTIFICATE UNDER 37 CFR 1.8**

I hereby certify that this paper or fee is being deposited with the United States Postal Service as first class mail in an envelope addressed to the Commissioner for Patents, P.O. Box 1450, Arlington, VA 2213-1450 on June 16, 2003.

By: Name: Trzcy Truick

55 South Lake Avenue, Suite 710 Pasadena, California 91101 June 16, 2003

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

We are transmitting herewith the attached:

- Transmittal Sheet in duplicate containing Certificate under 37 C.F.R. 1.8
- Supplemental Information Disclosure Statement (37 C.F.R. §1.97(b)(3))
- Form 1449 (Information Disclosure Statement)
- Exhibits 190-232
- Return postcard

Please charge any and/or additional fees or credit overpayment to Deposit Account No. 50-0306. A duplicate of this sheet is enclosed.

MANDEL & ADRIANO

55 South Lake Avenue, Suite 710 Pasadena, California 91101 (626)395-7801 Name: Sarah B. Adriano

Reg. No.: 34,470 Initials: SBA

Customer No. 26,941



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BY BLOCKING LYMPHOCYTIC SIGNALS AND BY BLOCKING LFA-1

MEDIATED ADHESION

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55 S. Lake Avenue, Suite 710 Pasadena, California 91101 June 16, 2003

# SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT (37 C.F.R. § 1.97(b)(3))

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Dear Sir:

This information Disclosure Statement should be considered because it is submitted before the mailing date of the first Office Action on the merits according to 37 C.F.R. §1.97(b)(3). In accordance with 37 C.F.R. §1.98(d), copies of Exhibits 190-232 as set forth in the Form 1449 are included herewith.

With regard to the above-identified application, the items of information listed on the enclosed Form 1449 are brought to the attention of the Examiner. They are as follows:

Robert Townsend, et al. Serial No. 09/877,987 Filed: June 8, 2001

Page 2

- International Publication No. WO 01/90122 A2 published November 29, 2001.
   (Exhibit 190)
- International Publication No. WO 01/54732 A1 published August 2, 2001.
   (Exhibit 191)
- International Publication No. WO 00/23115 published April 27, 2000. (Exhibit 192)
- International Publication No. WO 97/28267 published August 7, 1997. (Exhibit 193)
- International Publication No. WO 96/14865 published May 23, 1996. (Exhibit 194)
- International Publication No. WO 98/31820 published July 23, 1998. (Exhibit 195)
- International Publication No. WO 94/28912 published December 22, 1994.
   (Exhibit 196)
- U.S. Patent No. 6,444,792 issued September 3, 2002. (Exhibit 197)
- International Publication No. WO 93/19767 published October 14, 1993. (Exhibit 198)
- International Publication No. WO 94/29436 published December 22, 1994.
   (Exhibit 199)
- International Publication No. WO 95/33823 published December 14, 1995.
   (Exhibit 200)
- International Publication No. WO 93/00431 published January 7, 1993. (Exhibit 201)
- European Patent Publication Number 0 613 944 A2 published September 7, 1994. (Exhibit 202)
- European Patent Publication Number 0 682 039 A1 published November 15, 1995.
   (Exhibit 203)
- Morton, Phillip A. et al., "Differential Effects of CTLA-4 Substitutions on the Binding of Human CD80 (B7-1) and CD86 (B7-2)," Journal of Immunology, 1996, 156:1047-1054 (Exhibit 204)
- Souza, D. et al., "Synergistic Inhibition of Established Collagen Induced Arthritis
  (CIA) Through Dual Inhibition of ICAM-1 and CD40L Pathways," Arthritis and
  Rheumatism, 1999, 42:S60 (Exhibit 205)

Robert Townsend, et al. Serial No. 09/877,987 Filed: June 8, 2001

Page 3

- U.S. Patent No. 5,968,510 issued October 10, 1999. (Exhibit 206)
- U.S. Patent No. 5,844,095 issued December 1, 1998. (Exhibit 207)
- International Publication No. WO 01/92337 published December 6, 2001
   (Exhibit 208)
- Alegre, Maria-Luisa et al., "Immunomodulation of Transplant Rejection Using Monoclonal Antibodies and Soluble Receptors," *Digestive Diseases and Sciences*, 1995, 40:58-64 (Exhibit 209)
- Murakami, Masaaki et al., "Identification and characterization of an alternative cytotoxic T lymphocyte-associated protein 4 binding molecule on B cells,"
   Proceedings of the National Academy of Sciences USA, 1995, 93:7838-7842

   (Exhibit 210)
- Peach, Robert J. et al., "Both Extracellular Immnunoglobin-like Domains of CD80
  Contain Residues Critical for Binding T Cell Surface Receptros CTLA-4 and CD28,"

  Journal of Biological Chemistry, 1995, 270:21181-21187. (Exhibit 211)
- Fargeas, Christine et al., "Identification of Residues in the V Domain of CD80 (B7-1) Implicated in Functional Interactions with CD28 and CTLA4," *Journal of Experimental Medicine*, 1995, 182:667-675. (Exhibit 212)
- Steurer, Wolfgang et al., "Ex Vivo Coating of Islet Cell Allografts with Murin CTLA4/Fc Promotes Graft Tolerance," *Journal of Immunology*, 1995, 155:1165-1174.
   (Exhibit 213)
- Guo, Yong et al., "Mutational Analysis and an Alternatively Spliced Product of B7
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Robert Townsend, et al. Serial No. 09/877,987 Filed: June 8, 2001 Page 4

- Rattis, Frédérique-Marie et al., "Expression and function of B7-1 (CD80) and B7-2 (CD86) on human epidermal Langerhans cells," *European Journal of Immunology*, 1996, 26:449-453. (Exhibit 216)
- International Publication No. WO 98/33,513 published August 6, 1998. (Exhibit 217)
- U.S. Patent No. 5,851,795 issued December 22, 1998 (Exhibit 218)
- U.S. Patent No. 5,958,403 issued September 28, 1999. (Exhibit 219)
- Najafian, Nader and Mohamed H. Sayegh, "CTLA4-Ig: a novel immunosuppressive agent," Exp. Opin. Invest. Drugs, 2000, 9:2147-2157 (Exhibit 220)
- Tan, Patrick et al., "Induction of Alloantigen-specific Hyporesponsiveness in Human T Lymphocytes by Blocking Interaction of CD28 with Its Natural Ligand B7/BB1,"
   Journal of Experimental Medicine, 1993, 177:165-173. (Exhibit 221)
- Turka, Laurence A. et al., "T-cell activation by the CD28 ligand B7 is required for cardiac allograft rejection in vivo," Proceedings of the National Academy of Sciences USA, 1992, 89:11102-11105. (Exhibit 222)
- U.S. Patent No. 5,770,197 issued June 23, 1998. (Exhibit 223)
- U.S. Patent No. 6,132,992 issued October 17, 2000. (Exhibit 224)
- U.S. Patent No. 5,773,253 issued June 30, 1998. (Exhibit 225)
- U.S. Patent No. 5,885,796 issued March 23, 1999. (Exhibit 226)
- U.S. Patent No. 5,977,318 issued November 2, 1999. (Exhibit 227)
- U.S. Patent No. 5,885,579 issued March 23, 1999. (Exhibit 228)
- U.S. Patent No. 5,993,800 issued November 30, 1999. (Exhibit 229)
- U.S. Patent No. 5,916,560 issued June 29, 1999. (Exhibit 230)
- Schwartz, R., "Costimulation of T Lymphocytes: The Role of CD28, CTLA-4, and B7/BB1 in Interleukin-2 Production and Immunotherapy," *Cell*, 1992, 71:1085-1088.
   (Exhibit 231)
- U.S. Patent No. 5,637,481 issued June 10, 1997 (Exhibit 232)

Robert Townsend, et al. Serial No. 09/877,987

Filed: June 8, 2001

Page 5

No representation is made that a reference is "prior art" within the meaning of 35 U.S.C. §§ 102

and 103 and Applicants reserve the right, pursuant to 37 C.F.R. § 1.131 or otherwise, to establish

that the references are not "prior art." Moreover, Applicants do not represent that the references

have been thoroughly reviewed or that any relevance of any portion of a reference is intended.

Consideration of the items listed is respectfully requested. Applicants invite the Patent Office to

request additional information if necessary. Pursuant to the provisions of M.P.E.P. 609, it is

requested that the Examiner return a copy of the attached Form 1449, marked as being considered

and initialed by the Examiner, to the undersigned with the next official communication.

No fee is deemed necessary in connection with the filing of this Information Disclosure Statement.

However, if any additional fee is required, authorization is hereby given to charge the amount of

any such fee, or credit any overpayment, to Deposit Account No. 50-0306.

Respectfully submitted,

Sarah B. Adriano

Registration No. 34,470

Sarah B. Ad

Teresa Liang

Registration No. 51,946

Practioners for Applicants

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## INFORMATION DISCLOSURE STATEMENT \( \) IN AN APPLICATION

(Use several sheets if necessary)

Docket Number D0009NP;30436.53USU1 Application Number 09/877,987

Applicant

Robert M. Townsend et al.

Filing Date

Group Art Unit

June 8, 2001

1645

**U.S. PATENT DOCUMENTS** SUBCLASS FILING DATE NAME CLASS DOCUMENT NO. DATE **EXAMINER** IF APPROPRIATE INITIAL September 3, 2002 Gray et al. 6,444,792 (Exhibit 197) October 10, 1999 Linsley et al. 5,968,510 (Exhibit 206) 5,844,095 December 1, 1998 Linsley et al. (Exhibit 207) December 22, 1998 Linsley et al. 5,851,795 (Exhibit 218) September 28, 1999. Strom et al. 5,958,403 (Exhibit 219) June 23, 1998 Linsley et al. 5,770,197 (Exhibit 223) October 17, 2000 Ledbetter et al. 6,132,992 (Exhibit 224) June 30, 1998 Linsley et al. 5,773,253 (Exhibit 225) Linsley et al. March 23, 1999 5,885,796 (Exhibit 226) November 2, 1999 Chou 5,977,318 (Exhibit 227) March 23, 1999 Linsley et al. 5,885,579 (Exhibit 228) 5.993.800 November 30, 1999 Linsley et al. (Exhibit 229) 5,916,560 June 29, 1999 Larsen et al.

FOREIGN PATENT DOCUMENTS						
 DOCUMENT NO.	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
					YES	NO
WO 01/90122 A2 (Exhibit 190)	November 29, 2001	PCT				
WO 01/54732 A1 (Exhibit 191)	August 2, 2001	PCT			_	
WO 00/23115 (Exhibit 192)	April 27, 2000	PCT				·- <u>-</u> -

Ledbetter et al.

June 10, 1997

**EXAMINER** 

(Exhibit 230)

5,637,481 (Exhibit 232)

DATE CONSIDERED

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form for next communication to the Applicant.

<sup>\*</sup>Substitute Disclosure Statement Form (PTO-1449) Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

FORM 1449*				DOCK	et Number		Thhiren	on Numb	4	- 1
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	(Exhibit 217)				<u> </u>	<u> </u>				

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)				
	Morton, Phillip A. et al., "Differential Effects of CTLA-4 Substitutions on the Binding of Human CD80 (B7-1) and CD86 (B7-2)," Journal of Immunology, 1996, 156:1047-1054 (Exhibit 204)			
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